

REMARKS/ARGUMENTS

This is meant to be a complete response to the Office Action mailed November 30, 2004. In the Office Action, the Examiner stated that restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 6-7, 10, 13, 15-16, 24-27, 44-47, drawn to a urinary tract tissue graft composition comprising embryonic stem cells and a segment of small intestinal submucosa, wherein said stem cell is seeded on the surface of the segment of a small intestinal submucosa, a method for making said graft and a method for using said graft, classified in class 435, subclass 1.1.
- II. Claims 1-3, 6-7, 10, 13, 15-16, 24-27, 44-47, drawn to a urinary tract tissue graft composition comprising adult stem cells and a segment of small intestinal submucosa, wherein said stem cell is seeded on the surface of the segment of small intestinal submucosa, a method for making said graft and a method for using said graft, classified in class 435, subclass 1.1.
- III. Claims 4-5, 8-9, 11-12, 14, 17-23, 28-43, 48-55, drawn to a urinary tract tissue graft composition comprising embryonic stem cells, a segment of small intestinal submucosa, and further comprising one cell type, wherein said cell type or said stem cell is seeded on the surface of the small intestinal submucosa, a method for making said graft and a method for using said graft, classified in class 435, subclass 1.1.
- IV. Claims 4-5, 8-9, 11-12, 14, 17-23, 28-43, 48-55, drawn to a urinary tract tissue graft composition comprising adult stem cells, a segment of small intestinal submucosa, and further comprising one cell type, wherein said cell type or said stem cell is seeded on the surface of the small intestinal submucosa, a method for making said graft and a method for using said graft, classified in class 435, subclass 1.1.

Applicants respectfully elect Group II, with traverse. The claims of the subject application have been amended to remove references to embryonic stem cells and thus cancel the invention of Groups I and III, without prejudice. Such inventions will be pursued in a divisional application. However, Applicants respectfully traverse the restriction requirement between Groups II and IV.

Group II relates to a urinary tract tissue graft composition comprising a segment of small intestinal submucosa (SIS) and at least one adult stem cell type seeded on the SIS. Group IV relates to one embodiment of the similar urinary tract tissue graft composition as Group II, that further includes at least one cell type selected from smooth muscle cells and urothelial cells also seeded on the SIS.

In support of the restriction, the Examiner stated that:

Whereas the inventions are related as being drawn to urinary tract tissue grafts, methods for making said grafts, and methods for using said grafts, the inventions comprise compositions that have different physical structures, functions, and utilities. For example, the urinary tract tissue grafts of groups I and II comprise at least one type of stem cell and a segment of small intestinal submucosa having a mucosal and serosal surface. In contrast, the urinary tract tissue grafts of groups III and IV comprise at least one type of stem cell, a segment of small intestinal submucosa, and further comprising at least one type of cell, wherein said cell is selected from the group consisting of smooth muscle cells and urothelial cells. The grafts of groups I and II comprising only a stem cell and small intestinal submucosa has a different physical structure, function and utility from the grafts of Groups III and IV which comprise a stem cell, a small intestinal submucosa, and a smooth muscle or urothelial cell. Therefore, because the inventions are different, each from the other, they are patentably distinct and will require a separate search in the patent and non-patent literature.

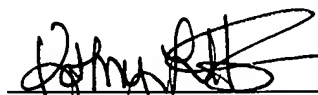
The Examiner's assertion that groups II and IV comprise compositions that have different physical structures, functions and utilities is incorrect. First, both compositions have the same function as urinary tract tissue graft compositions. Second, both compositions have the same utility, again as tissue grafts for the urinary tract. Third, the purpose of using stem cells is because they have the potential to regenerate tissue by differentiating into one or more different cell types. In the case of a urinary tract tissue graft composition, the stem cells would have to differentiate into smooth muscle cells and/or urothelial cells, as these are the cell types that constitute a urinary tract tissue. Therefore, the addition of smooth muscle cells and/or urothelial cells to the composition would not be a patentably distinct structure, and thus Groups II and IV are not recognized as divergent subject matter.

Also for the reasons stated hereinabove, a separate, non-coextensive search of the patent and non-patent literature will not be required, and therefore Applicants respectfully submit that restriction between Groups II and IV for examination purposes is not proper.

Applicants respectfully request reconsideration and withdrawal of the restriction requirement under 35 U.S.C. 121 for Groups II and IV.

Should the Examiner have any questions regarding this amendment or the remarks contained therein, Applicants' representative would welcome the opportunity to discuss the same with the Examiner.

Respectfully submitted,



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